

EPA Reg. No. 2596-166
Vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 27, 2015

Cristina Griffin
Agent
The Hartz Mountain Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: Condition of Registration –Storage Stability and Corrosion Characteristics Data
Product Name: Hartz Reference # 130
EPA Registration Number: 2596-165
Application Date: March 25, 2015
Decision Number: 503499

Dear Ms. Griffin:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Letu Kassa by phone at 703-347-0462, or via email at kassa.letu@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATE ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION(7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

Date Out: October 8, 2015

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☐; ONE YEAR STUDY ☒;
OVER 1 YEAR STUDY ☐
MP ☐ EP ☒ EUP ☐ ACTION CODE: 570
DP BARCODE No.:426951 REG. No.: 2596-165
DECISION No.: 503499 MRID Nos. : 496150 -01 and 495980-01
PRODUCT NAME: HARTZ® REFERENCE # 130
COMPANY: THE HARTZ MOUNTAIN CORP.

FROM: William Herald, Microbiologist (MS) /Chemist, NEHA/REHS/Registered Sanitarian
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch RD (CITBA) (7505P)

TO: Julie Chao / Kable B. Davis PM 3
Invertebrate and Vertebrate Branch 1 / RD (7505P)

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):

☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):

☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

DATE OUT: October 8, 2015

DP BARCODE No.: 426951

REG. No.: 2596-165

DECISION No.: 503499

MRID Nos. : 496150 -01 and 495980-01

PRODUCT NAME: HARTZ® REFERENCE # 130

COMPANY: THE HARTZ MOUNTAIN CORP

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient: Fipronil and (S)-Methoprene

Label claims Nominal concentrations (%): 9.8% and 8.85% respectively

Initial concentration(s) of the AI(s) (%) used in the study: 10.090% and 8.630% respectively

Lower certified limits (%) based on AI % in the study: 9.856% and 8.199% respectively

C. EXPERIMENTAL PARAMETERS

Temperature: Environmental chamber 25°C

Relative Humidity: 50%

Duration of study: ☒ 1 year; ☐ over 1 year

Type of container: White polypropylene tubes provided by the manufacturer.

Analysis at intervals: ☒ 0 (initial); ☒ 3 months; ☒ 6 months ☒ 9 months; ☒ 12 months

D. ANALYTICAL METHOD

Method	Detector
Gas Chromatography (GC)	Flame Ionization Detector (FID)

E. RESULTS

The report shows that following the initial characterization of the AI:

- 1) After storage in an environmental chamber set at 25°C for periods of 3, 6, and 9 Months the second AI %, (S)-Methoprene remained well within statutory parameters recited in Title 40 United States Code of Federal Regulations § 158.350. But the first AI%, Fipronil appears to have fallen over 0.35% by the 3rd month; however, by the 6th month testing period it regained slightly and then slightly fell for the subsequent testing periods. These slight differences between testing intervals appear to be negligible; however, the label should indicate a shelf life of not more than one year.
- 2) After 12 months at RT there were no packaging changes reported in the study and that there were no significant weight changes.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 26, 2014

Mr. Sean McNear
Senior Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

**Subject: Amended Labeling; Submission of Efficacy Data to Support New Speed of Kill Claim
Hartz® Reference #130, EPA Reg. No. 2596-165
Your Submission Dated June 7, 2013 & E-Resubmission Dated February 26, 2014**

Dear Mr. McNear:

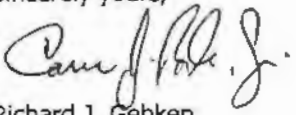
The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted" as well as copies of the efficacy review and review for minimum treatment weight that were completed for the referenced product amendment are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,


Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: Label Stamped "Accepted," dated February 26, 2014
Efficacy Review, dated December 6, 2013
Review for Minimum Treatment Weight, dated November 5, 2013

002596-00165 D479892

Hartz® Reference # 130

Alternate Brand Names

Hartz® Force Plus™ Dual Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® Field Force Plus™ Dual Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Plus™ Dual Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Plus™ Dual Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Plus Force™ for Dogs (&) (and Puppies)
Hartz® FieldForce Plus™ for Dogs (&) (and Puppies)
Hartz® First Defense Plus™ for Dogs (&) (and Puppies)

Hartz® Plus Force™ Dual Action Topical Solution for Dogs (&) (and Puppies)
Hartz® FieldForce Plus™ Dual Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Plus™ Dual Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Plus™ Dual Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Plus™ Dual Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Plus™ Dual Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Plus™ Dual Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Plus™ for Dogs (&) (and Puppies)
First Defense Plus™ for Dogs (&) (and Puppies)
FieldForce Plus™ Dual Action Topical Solution for Dogs (&) (and Puppies)
First Defense Plus™ Dual Action Topical Solution for Dogs (&) (and Puppies)
First Defense Plus™ Dual Active Topical Solution for Dogs (&) (and Puppies)

FRONT PANEL

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.
Weighing 23 to 44 lbs.
Weighing 45 to 88 lbs.
Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....9.80%
(S)-Methoprene.....8.80%

OTHER INGREDIENTS 81.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

ACCEPTED
February 26, 2014
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:
EPA. Reg. No. 2596-165

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

For use ONLY on DOGS and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.) 0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.] DO NOT USE ON CATS

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents) you may call 1-800-275-1414 twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

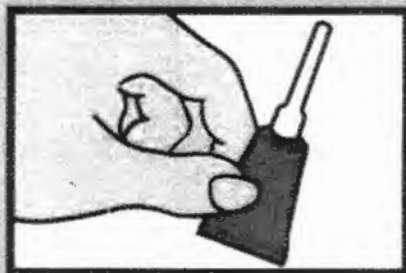
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS.

DIRECTIONS FOR USE

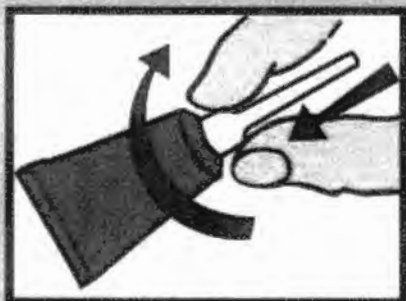
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

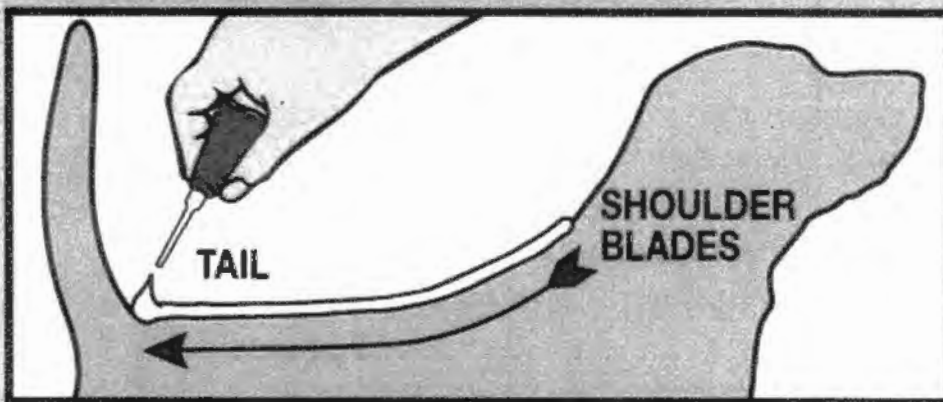
THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-165
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

[Product name]

Only for use on DOGS AND PUPPIES 8 WEEKS OR OLDER

[The appropriate size and fill volume will be correctly used on each applicable dog's weight category]

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-165

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs and puppies 8 weeks or older)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs and puppies 8 weeks or older)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

Prevents establishment of new infestations after application on premises

Prevents establishment of new infestations in the home environment

Prevents establishment of new infestations on premises

Starts killing new fleas within 30 minutes*

*48 hours after initial application

[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice
Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on dogs and puppies 8 weeks or older) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on dogs and puppies 8 weeks or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on dogs and puppies 8 weeks or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home environment

Contains two unique ingredients to prevent flea infestations on premises

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Easy spot on topical applicator

Patents Pending

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can be used on breeding, pregnant and lactating bitches

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (Product name)

effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,

and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial Limited.

Only for dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, second month, third month
Value pack
3 month supply
3 monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
3 Pro-cision Flo® Applicator(s) (included)
(Pro-cision Flo® Applicator)

Direct to your dog's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

DATA PACKAGE BEAN SHEET

Date: 24-Apr-2015

Page 1 of 2

Decision #: 503499

DP #: (426951)

NON PRIA

Parent DP #:

Submission #: 966134

E-Sub #:

*** Registration Information ***

Registration: 2596-165 - HARTZ REFERENCE #130

Company: 2596 - THE HARTZ MOUNTAIN CORPORATION

Risk Manager: RM 03 - Kable Davis - (703) 306-0415 Room# PY1 S-7723

Risk Manager Reviewer: Julie Chao JCHAO

Sent Date: 26-Mar-2015

PRIA Due Date: 14-Jul-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (570) CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRED; REQUIRES RD REVIEW

Ingredients: 105402, S-Methoprene(8.8%)

129121, Fipronil(9.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 24-Apr-2015

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: Storage Stability and Corrosion Characteristics

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / CITAB

Last Possible Science Due Date: 05-May-2015

Team Name: CHEM

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

ATTN: Chemistry Team

Please review the enclosed storage stability and corrosion characteristics study for EPA Reg. No. 2596-165. Copies of the submission cover letter, current Basic CSF, and current label are enclosed. Thank you.

DP#: (426951)

*** Studies Sent for Review ***

Decision#: (503499)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49598001		Needham, L. (2013) GLP Stability Report for Hartz Fipronil/Methoprene Topical. Project Number: CPD/2011/23. Unpublished study prepared by The Hartz Mountain Corporation. 8p.	830.6317/Storage stability	Pass (18-Apr-2015)
49598001		Needham, L. (2013) GLP Stability Report for Hartz Fipronil/Methoprene Topical. Project Number: CPD/2011/23. Unpublished study prepared by The Hartz Mountain Corporation. 8p.	830.6320/Corrosion characteristics	Pass (18-Apr-2015)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 08, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DELTA ANALYTICAL CORPORATION
THE HARTZ MOUNTAIN CORPORATION
12510 PROSPERITY DRIVE SUITE 160
SILVER SPRING, MD 20904

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 26-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



J598000

March 25, 2014

Document Processing Desk (RESPONSE)
US EPA, Office of Pesticide Programs (7504P)
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington, VA 22202

Attn: Kable Davis, PM 3

Re: **Submission of Storage Stability, Corrosion Study to Fulfill Conditions of
Registration; No PRIA Fee. Cover Letter and Data Transmittal**

Product: Hartz Reference #130
Company: The Hartz Mountain Corporation
File Symbol: 2596-165

Dear Mr. Davis:

In response to the request from EPA, I am submitting a storage stability and corrosion characteristics study on behalf of The Hartz Mountain Corporation. The data are enclosed and listed below. An affidavit at the end of each study ties the study to the EPA product name.

Enclosures:

- Application for Pesticide Registration (EPA Form 8570-1)
- Agent letter
- Certification with Respect to Citation of Data
- Data Matrix (Internal and Public File Copy)
- Data (3 copies):
 - Volume 1 of 1: GLP Stability Report for Hartz Fipronil/Methoprene Topical;
 - Guidelines 830.6317 and 830.6320

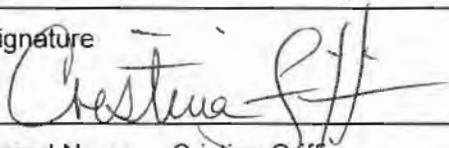
MRID: **49598001**

If you have any questions regarding this submission, please contact me at (301) 680-7971 or cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin, Agent
The Hartz Mountain Corporation

cc: David Jones, Hartz

United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number Response				
Application for Pesticide - Section I							
1. Company/Product Number 2596-165		2. EPA Product Manager: Kable Davis					
4. Company/Product Name The Hartz Mountain Corporation / Hartz Reference #130		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted					
5. Name and Address of Applicant (Include Zip Code) The Hartz Mountain Corporation c/o Delta Analytical Corporation 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 <input type="checkbox"/> Check if this is new address		6. Expedited Review. In accordance with FIFRA Sec. (3)(c)(3)(b)(i), my product is similar or identical in composition and labeling to : EPA Reg. No.: Product Name:					
Section II							
<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated: <input type="checkbox"/> Notification		<input type="checkbox"/> Final printed labels in response to Agency letter dated <input type="checkbox"/> "MeToo" Application <input checked="" type="checkbox"/> Other - Explain Below					
Explanation: Use additional page(s) if necessary. (For sections I and II.) Submission of Storage Stability/Corrosion Characteristic Study to Fulfill Conditions of Registration PRIA Assessment: No fee required; email contact: cgriffin@delta-ac.com							
Section III							
1. Material This Product Will Be Packaged In :							
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No Certification must be submitted	Unit Packaging <input type="checkbox"/> yes <input type="checkbox"/> no <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">If Yes, Unit packaging weight</td> <td style="width: 50%;">No. per container</td> </tr> </table>	If Yes, Unit packaging weight	No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">If Yes, package weight</td> <td style="width: 50%;">No. per container</td> </tr> </table>	If Yes, package weight	No. per container	2. Type of container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other: (Specify)
If Yes, Unit packaging weight	No. per container						
If Yes, package weight	No. per container						
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product				
6. Manner in which Label is affixed to product: <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other							
Section IV							
1. Contact Point							
Name Cristina Griffin		Title: Agent, The Hartz Mountain Corporation	Telephone No.: 301 680-7971				
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			Date Application Received (Stamped)				
2. Signature 		3. Title: Agent, The Hartz Mountain Corporation					
4. Typed Name Cristina Griffin		5. Date March 25, 2015					



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 23, 2015

Document Processing Desk (COADR)
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington DC 20460

Dear Sir/Madam:

I appoint:

Delta Analytical Corporation
12510 Prosperity Drive
Suite 160
Silver Spring, MD 20904

Telephone: 301-680-7971
Fax: 301-680-7975

as the designated agent of Hartz Mountain Corporation, EPA Company Number 2596, to act in all matters concerning registration of its products with US EPA. This designation of agent is effective immediately and supersedes all previous agent designations. Cristina Griffin (cgriffin@delta-ac.com) and Jeff Jones (jjones@delta-ac.com) will be the primary contacts at Delta Analytical.

Sincerely,

A handwritten signature in dark ink, appearing to read "David Jones", written over a horizontal line.

David Jones
Manager Regulatory Affairs

UNI TATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation c/o Delta Analytical Corporation, 12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904	EPA Registration Number/File Symbol 2596-165
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-methoprene	Date March 25, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) indoor non-food	Product Name Hartz Reference #130

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

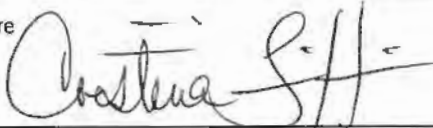
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine for imprisonment or both under applicable law.

Signature 	Date March 25, 2015	Typed or Printed Name and Title Cristina Griffin, Agent The Hartz Mountain Corporation
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
Washington, DC 20460

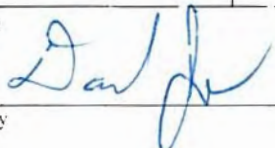
Form Approved OMB No. 2010-0060

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DATA MATRIX – END USE

Date: February 23, 2015		EPA Reg No./File Symbol	2596-165	Page 1 of 3	
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

PRODUCT CHEMISTRY – PROD. IDENTITY, COMP. & ANALYSIS

830.1550	Product Identification and composition	48379002	The Hartz Mountain Corporation	Own	
830.1600	Beginning materials	48379002	The Hartz Mountain Corporation	Own	
830.1650	Description of formulation process	48379002	The Hartz Mountain Corporation	Own	
830.1670	Formation of impurities	48379002	The Hartz Mountain Corporation	Own	
830.1750	Certified limits	48379002	The Hartz Mountain Corporation	Own	
830.1800	Enforcement analytical method	48379003	The Hartz Mountain Corporation	Own	
830.6302	Color	48379001	The Hartz Mountain Corporation	Own	Self-certification
830.6303	Physical State	48379001	The Hartz Mountain Corporation	Own	Self-certification
830.6304	Odor	48379001	The Hartz Mountain Corporation	Own	Self-certification
830.6314	Oxidation / Reduction	NA	NA	NA	Not applicable: None of the components of the product is expected to act as an oxidant or reductant.
830.6315	Flammability	48379001	The Hartz Mountain Corporation	Own	Self-certification
830.6316	Explodability	NA	NA	NA	Not applicable: End use products is not potentially explosive
830.6317	Storage stability	48379001 To be assigned	The Hartz Mountain Corporation	Own	
830.6319	Miscibility	NA	NA	NA	Not applicable: End use product is not to be diluted with petroleum solvents
830.6320	Corrosion Characteristics	48379001 To be assigned	The Hartz Mountain Corporation	Own	
Signature 		Name and Title David Jones/Mgr. Regulatory Affairs		Date February 23, 2015	

Internal copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 401 M. Street, S.W.
 Washington, DC, 20460

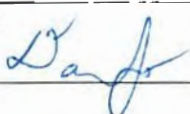
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DATA MATRIX – END USE

Date: February 23, 2015	EPA Reg No./File Symbol	2596-165	Page 2 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Product Hartz Reference #130	
Ingredient Fipronil, (S)-methoprene			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter
			Status
			Note

830.6321	Dielectric breakdown voltage	NA	NA	NA	Not applicable: End use product is not to be used around electrical equipment
830.7000	pH	NA	NA	NA	Not applicable: End use product is not to be dispersed with water.
830.7100	Viscosity	48379001	The Hartz Mountain Corporation	Own	Self-certification
830.7300	Density	48379001	The Hartz Mountain Corporation	Own	Self-certification
TOXICITY					
870.1100	Acute oral toxicity	43951703	Merial Inc.	PAY	Offer to pay 2/11/11
870.1200	Acute dermal toxicity	44487701	Merial Inc.	PAY	Offer to pay 2/11/11
870.1300	Acute inhalation toxicity	44433302	Merial Inc.	PAY	Offer to pay 2/11/11
870.2400	Acute eye irritation	44942006	Merial Inc.	PAY	Offer to pay 2/11/11
870.2500	Acute dermal irritation	44942007	Merial Inc.	PAY	Offer to pay 2/11/11
870.2600	Skin sensitization	44942008	Merial Inc.	PAY	Offer to pay 2/11/11

PREVENTION/MITIGATION OF ADVERSE EFFECTS – SAFETY PACKAGING

NA	Child Resistant Package Test	48684602 48684603 48684604 48684605 48684606	The Hartz Mountain Corporation	Own	
Signature 	Name and Title David Jones/Mgr. Regulatory Affairs		Date February 23, 2015		

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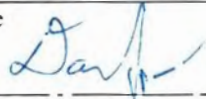
DATA MATRIX – END USE

Date: February 23, 2015		EPA Reg No./File Symbol		2596-165		Page 3 of 3					
Applicant's/Registrant's Name & Address		Product									
The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Hartz Reference #130									
Ingredient Fipronil, (S)-methoprene											
Guideline Reference Number		Guideline Study Name		MRID Number		Submitter		Status		Note	

PRODUCT PERFORMANCE

810.3300	Treatment to Control Pests of Humans and Pets	44942105 44942106 45612701 45620501 45620504 45620505 45620506 45866901 45866902	Merial Inc.	PAY PAY PAY PAY PAY PAY PAY PAY PAY	Offer to pay 2/11/11
810.3300	Treatment to Control Pests of Humans and Pets	49153901	The Hartz Mountain Corporation	Own	

DOMESTIC ANIMAL SAFETY

870.7200	Domestic Animal Safety	43863802 45612702 45620507 45143901	Merial Inc.	PAY PAY PAY PAY	Offer to pay 2/11/11
Signature 	Name and Title David Jones/Mgr. Regulatory Affairs		Date February 23, 2015		

